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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,432	08/07/2003	Luc Uylenbroeck	2003_1110	8533

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EXAMINER
SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,432	UYLENBROECK ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-21* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Amendment filed July 21, 2004 is acknowledged. Claims 1-11 are canceled. New claims 12-21, directed to a patient population of an infant or child, are presented and represent all of the claims now under consideration.

Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Original claim 1, directed to a use of cetirizine, an isomer thereof or a pharmaceutically acceptable salt thereof, for the preparation of a medicament, does not provide support for new claim 21. Original claim 1 did not set forth any steps involved in a method of making a pharmaceutical composition. Further search and consideration are required.

Since Applicants have received an Action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The rejection of claim 11 under 35 U.S.C. 112, first paragraph, in the First Action, as based on a disclosure that is not enabling, is moot following the cancellation of the claim.

A Terminal Disclaimer filed under 37 CFR 1.321 is acknowledged. Accordingly, the rejection of record under the judicially created doctrine of obviousness-type double patenting over the claims of U.S. Patent 6,432,961 is withdrawn.

In the last Office Action claims 1-11 were rejected under 35 U.S.C. 102(b) as being anticipated by Trieloff, I., TW Padiatrie. It was asserted Trieloff teaches the administration of cetirizine to prevent asthma.

Applicants argue this publication was based on an attempt to improve recruitment to the study and because the reference contained no results of the study, Applicants urge the reference is not enabling and does not provide a reasonable expectation of success.

Applicants' assertion that this publication was based on an attempt to improve recruitment to the study is without support. The Trieloff document was cited on the Information Disclosure Statement filed August 7, 2003. Accordingly, a complete copy of the article – preferably in English - is requested when Applicants respond to this Office Action. It is further noted in another reference cited on the same Information Disclosure Statement, Businco et al., Minerva Pediatrica, as well as in Fortschritte der Medizin, that early allergy treatment with cetirizine, as in the case of patients with atopic dermatitis, can prevent asthma.

Until such time that no reasonable expectation of success can be clearly shown, the rejection of record under 35 U.S.C. 102(b) is maintained. The claimed pharmaceutically acceptable salt, dosage range, dosing regimen and mode of administration are well established in the prior art. The prior art broadly teaches the administration of cetirizine to prevent asthma in children at risk.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 571-272-0585.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

October 7, 2004